DuPont Haskell Global Centers
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February 5, 2010

Via Federal Express

Document Processing Center (Mail Code 7407M)
Room 6428
Attention: 8(e) Coordinator
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency, ICC Building
1201 Constitution Ave., NW
Washington, DC 20004

Dear 8(e) Coordinator:

8EHQ-06-16436/8EHQ-06-16478

This letter is to inform you of the preliminary results of a developmental toxicity study in rats with the above referenced test substance. This test substance is subject to a Consent Order, PMN P-08-509.

Groups of 22 time-mated Crl:CD(SD) rats were administered solutions of the test substance in deionized water at dose levels of 0, 10, 100, or 1000 mg/kg/day. Dosing was initiated on gestation day (GD) 6 and continued through GD 20. During the in-life portion of the study, maternal body weights and food consumption as well as clinical observations data were collected. On GD 21, dams were euthanized and underwent a gross external and internal examination. Weights for maternal livers and kidneys were recorded and these tissues were preserved for future histopathologic examination. The gravid uteri were removed, weighed, and dissected. Uterine contents were described and fetuses were counted, weighed, sexed, and examined for external, visceral, head, and skeletal alterations.

There was a dose-related increase in the number of dams found with early deliveries in their cages on the morning of GD 21. There were 0, 0, 4, and 9 dams found delivered at 0, 10, 100, and 1000 mg/kg/day, respectively. In addition, mean fetal weight was 8 and 28% lower than controls at 100 and 1000 mg/kg/day, respectively; these reductions were statistically significant. Slight reductions in maternal body weight and food consumption occurred at 1000 mg/kg/day. Maternal kidney weights were significantly higher at 1000 mg/kg/day and maternal liver weights were significantly higher at 100 and 1000 mg/kg/day. The remaining data collected to date were generally comparable to control group data across all groups tested. There were no test substance-related increased in fetal resorptions, malformations, or variations at any dose level tested. Maternal histopathology examinations are currently in progress.

This information is submitted in accordance with current guidance issued by EPA indicating EPA's interpretation of Section 8(e) of the Toxic Substances Control Act or, where it is not clear that reporting criteria have been met, it is submitted as a precautionary measure and because it is information in which EPA may have an interest.

Sincerely,

[redacted]

A. Michael Kaplan, Ph.D.
Director - Regulatory Affairs

AMK/SMM: clp
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